K090921

Attachment 2 – 510(k) Summary

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Beiersdorf

Beiersdorf Inc

187 Danbury Road
Wilton, CT 06897
Telephone (203) 563-5800

510(k) Summary

General Information:

Date of Summary Preparation: December 16, 2009

DEC 18 2009

Name and Address of Manufacturer:	Beiersdorf, Inc. 187 Danbury Road Wilton, Connecticut 06897
Contact Person:	Rosemary Barvenik Manager, Regulatory Affairs Telephone: (203) 854-8040 Fax: (203) 563-5890
Trade Name:	Anti-Embolism Stockings
Common Name:	Medical Support Stocking
Regulation Number:	21 CFR 880.5780(a)
Classification Name:	Medical Support Stocking
Regulatory Class:	II
Classification Panel:	General Hospital
Product Code:	DWL

K090921

Predicate Devices:	K040353 Flight Sock
	K032325 Jobst Travel Socks
	K925643 RX FIT Medical Stockings
	K830696 VENES Anti-Embolism Stocking
	K091141 Therafirm Anti-Embolism Stockings and Therafirm Men's Trouser Socks and Women's Trouser Socks
	Kendall T.E.D. Anti-Embolism Stockings
	(510(k) number unknown)
	TRUFORM Anti-Embolism Stockings
	(510(k) number unknown)

Indications for Use:

The Anti-Embolism Stockings:

- Help prevent edema and leg discomfort, and help prevent deep vein thrombosis (DVT) in individuals subjected to immobility.
- Over-the-Counter (OTC) Use

Device Description: The Anti-Embolism Stockings are compression stockings consisting of 90% nylon and 10% spandex. The thigh length stockings have a silicone band at the top. Knee length and thigh length models are each provided in three (3) different sizes.

The Anti-Embolism Stockings are designed for the post-operative patient.The knee and thigh length models of these anti-embolism stockings are produced on a circular knitting machine. Nylon yarns are knit into the fabric structure while the nylon covered spandex yarns are in-laid into the fabric structure. The stockings are designed with the higher compression in the ankle region (18 mmHg) and lower, graduated compression in the calf (11 mmHg) and thigh regions (8 mmHg - thigh length model) of the leg. The mechanism of action is achieved via the graduated compression design.

The Anti-Embolism Stockings are not made with natural rubber latex.

Substantial Equivalence: The Anti-Embolism Stockings are substantially equivalent to predicates with respect to the intended use, indications for use, and the technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 18 2009

Ms. Rosemary Barvenik
Regulatory Affairs Manager
Beiersdorf, Incorporated
187 Danbury Road
Wilton, Connecticut 06897

Re: K090921
Trade/Device Name: Anti-Embolism Stockings
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: December 3, 2009
Received: December 3, 2009

Dear Ms. Barvenik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

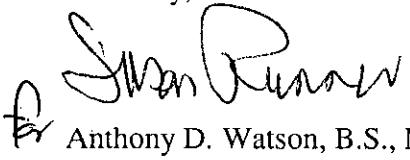
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090921

Indications for Use

510(k) Number (if known): K090921

Device Name: Anti-Embolism Stockings -
Models 71055-, 71057-, 71059-, 71064-, 71065-, 71068-00000-02

Indications for Use:

The Anti-Embolism Stockings:

Help prevent edema and leg discomfort, and help prevent deep vein thrombosis (DVT) in individuals subjected to immobility.

- Over-the-Counter (OTC) Use

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR **Over-The-Counter Use** X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR CLZ

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090921